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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,482	10/13/2000	Richard Derose	PH 97089	3435

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EXAMINER

MARX, IRENE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 05/21/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/582,482

Applicant(s)

Derose et al.

Examiner

Irene Marx

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for ReplyA SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 29, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 11 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

The amendment filed 3/29/02 is acknowledged. Claims 1-8 and 11 are being considered on the merits.

Claims 1-8 and 11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a method that is "characterized in that it consists in carrying out in a plant cell modified to produce" two suitable enzymes to bioconvert HPP to HPA and to HMO. In contrast, the specification only provides guidance for the bioconversion reaction with bacterial protein extracts from a strain of *Arthrobacter globiformis* and a strain of *Pseudomonas acidovorans*. (Specification, Examples 1-3). The only mention of a "modified plant" is the broad recitation at Specification, page 4, lines 16-19 wherein it is contemplated to use "a single biological organism which has been modified so as to produce the two enzymes. This biological organism can be a bacterium, a yeast or a plant cell". This speculative recitation demonstrates that applicant had no conception of the nature of the modification required to genetically engineer or transform a plant, from example. There is no indication that applicants had conception of the genes involved in encoding the proteins having the required activity at the time the claimed invention was made. Applicant has a "wish to know" how a plant cell might produce the two enzymatic activities in tandem to achieve the required chemical reaction, but there is no evidence of record that the gene or genes have been identified, necessary to encode the enzymes so as to carry out the modification envisioned in the plant cell. No guidance is presented for the identification of the gene or genes necessary for the specific enzymatic reactions required or for the preparation of plant cells having the required enzymatic capabilities, and no guidance is presented regarding the evaluation of the gene or genes and their respective sequences in plant cells necessary to effect gene expression of the enzymes of interest in the process of biocatalysis as claimed.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the claimed invention.

See *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene (or promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence), and at page 1027, where it is taught that the disclosure of a few gene sequences did not enable claims broadly drawn to any analog thereof.

See *In re Deuel* (CA FC) 34 USPQ2d 1210 (3/28/1995), wherein a reference to a partial protein sequence was not deemed to provide a written description for the respective human DNA sequence. In contrast, in the instant case there is not even the partial sequence of a protein that the DNA encodes, but rather applicants only have knowledge of bacterial extracts that can be used to effect a chemical reaction.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague, indefinite and confusing in the phrase "characterized in that it consists in carrying out in a plant cell modified to produce a first suitable enzyme...and a second suitable enzyme". There is no clear indication in the present written disclosure regarding the modifications envisioned to obtain "suitable enzymes", even when reading the claims in light of the specification. See also the written description rejection *supra*.

Claim 3-4, 6-8 and 11 are vague indefinite and confusing in failing to find proper antecedent basis in claim 1 for HPP-oxidase, respectively HPA-hydroxylase that originates from bacteria that can grow on HPA as the only carbon source. Claim 1 is directed to a modified plant as the enzyme producer.

Claim 11 is confusing in that the phrase "in the presence of an HPPD inhibitor" is unclear as to what is intended. The nature of an HPPD inhibitor is uncertain and it cannot be ascertained what constitutes "a suitable reaction medium" for an unknown substance in a plant cell. What does this substance inhibit, i.e., what is HPPD? Also, it cannot be ascertained whether the mere "presence" of such a substance is sufficient to achieve the desired results.

No claim is allowed.

The rejections under 35 U.S.C § 102 and 103 are withdrawn in view of applicant's amendments, but will be reinstated as appropriate upon removal of the new matter.

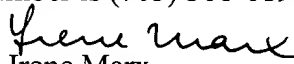
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.


Irene Marx
Primary Examiner
Art Unit 1651